

Consumers Union

Publisher of Consumer Reports

August 18, 2004

Dr. Lester Crawford, Acting Director
Food and Drug Administration
5600 Fishers Lane, Room 1471
Mail Stop HF-1
Rockville, Maryland 20857

Dear Dr. Crawford:

This letter concerns the most recent effort by the Bayer Corporation to further delay enforcement of FDA's well-founded decision to withdraw approval for the use of Baytril and other fluoroquinolone antibiotics in poultry.

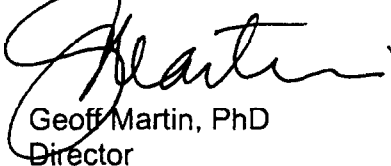
It has been more than three years since FDA first proposed this rule to safeguard the efficacy of this important class of drugs for human medicine and nearly six months since the Administrative Law Judge (ALJ) rejected Bayer's appeal of FDA's ruling. During that time, Abbott Laboratories, the only other company that has marketed a fluoroquinolone for use in poultry, has properly removed their product, sarafloxacin, from the market. However, Bayer's continued refusal to comply can only serve to increase the population of human pathogens that are resistant to fluoroquinolones, putting greater numbers of consumers who contract foodborne illness at risk of more serious or prolonged infections, or even death. Clearly the time for enforcement is past due. Bayer has had its day in court and lost. It is incumbent upon the FDA to act quickly to protect public health.

Consumers Union strongly agrees with the ALJ's opinion, as well as the scientific findings of the FDA, the Centers for Disease Control, and the American Medical Association, which conclude that continued use of fluoroquinolones in poultry presents a clear and compelling threat to public health.

Our own test of bacteria isolated from a nationally representative sample of store-bought chicken is among the largest studies showing increased resistance to fluoroquinolones in *Campylobacter*. A copy of the article is enclosed.

We urge you to act quickly to uphold the FDA decision and take immediate enforcement action to require Bayer to halt all use of Baytril in poultry.

Sincerely,



Geoff Martin, PhD
Director
Consumer Sciences



Carolyn Cairns
Senior Project Leader
Public Service Projects

Enc. 1

cc: Docket No. 00N-1571
Stephen F. Sundlof, Director, Center for Veterinary Medicine, FDA
Attila Molnar, President and CEO, Bayer Corporation
Senator Olympia Snowe
Senator Edward Kennedy
Congresswoman Sherrod Brown
Congressman Wayne Gilchrest